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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,068	08/26/2000	Ralph Evan McGinnis		6879

7590 10/19/2004  
Robert McGinnis  
1575 West Kagy Boulevard  
Bozeman, MT 59715

EXAMINER

HORLICK, KENNETH R

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/623,068	<b>Applicant(s)</b> MCGINNIS ET AL.	
	<b>Examiner</b> Kenneth R Horlick	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7/2/04, 7/21/04, and 8/3/04.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-5,8,20,21,33-35,38,50,51,78-80,83,95 and 99-171 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5,8,20,21,33-35,38,50,51,78-80,83,95 and 99-101 is/are allowed.
- 6) ☒ Claim(s) 102-171 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

1. Claim 102 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This apparatus claim is confusing because it cannot be determined from the specification what structural components satisfy the recited "means plus function" language. The claims require "means for determining information..." and "means for generating a physico-chemical signal...information...". Current practice under 35 U.S.C. 112, sixth paragraph requires that "means plus function" language in claims be limited to the "means" as set forth in the specification. However, the instant specification does not appear to describe even a single specific embodiment of what apparatus components are to be construed as the "means" in the claims. The portions of the specification pointed out in the prior response, at page 6, merely describe the apparatus in terms of functional definition, rather than exemplify an actual apparatus and its structural elements. The general description of "oligonucleotide technology" and "mass spectrometry" in the specification does not remedy this problem, as this does not set forth any structural components of an apparatus.

In the response filed 07/18/03 it is argued that the specification discusses embodiments of apparatus components with specific structural elements. Copies of articles describing such components, which were incorporated by reference in the specification, were supplied. However, it is submitted that it is still not possible to understand what apparatus is contemplated in the claim. The specification and noted references merely refer to a myriad of admittedly well known technologies and devices used therein; there is clearly no indication in the specification as to what actual

elements or components are contemplated in the claimed apparatus, let alone why such an apparatus might be patentable. It is suggested that if applicants are interested in apparatus-type claims in future applications, they may wish to consider non-means plus function claims which clearly specify the apparatus components.

2. With respect to the above rejection, the arguments of the response filed 07/02/04 have been fully considered, but are not found persuasive. Firstly, applicant is reminded that according to 35 U.S. C. 112, sixth paragraph practice examples in the specification are limiting with respect to the claims. While claim 102 has been amended in an attempt to further define the two "means" required in the claimed apparatus, nonetheless all of the issues raised in the rejection still apply. It is submitted that applicant is attempting to define the "means" by merely referring to a general methodology, such as oligonucleotide hybridization or signal generation for detection purposes. However, this still in no way makes clear what actual physical components are required in the claimed apparatus, and so there is still no basis for searching the prior art for such an apparatus nor basis for evaluating patentability on such an apparatus. And since the response again points out examples using well known technologies such as high density arrays, it is unclear what in the claimed apparatus is believed to contribute to patentability. It is submitted that the set of one or more oligonucleotides which the response argues about on page 36 cannot be properly read into the claim.

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3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 103-171 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 39 of the response it is stated that "extensive amendments to most of previously added claims 102 to 159 have been made"... "however all of these claims are still based on the new two-dimensional CL-F approach". However, the response does not specifically point out the basis in the specification for any of the numerous amendments, some of which are very detailed; thus, said amendments represent new matter. Similarly, the response does not point to basis for any of new claims 160-171. If applicant traverses this rejection, it is requested that it be pointed out with particularity (e.g., page/line numbers) where in the specification there is support for every amendment, as well as for limitations in new claims 160-171.

4. Claims 3-5, 8, 20, 21, 33-35, 38, 50, 51, 78-80, 83, 95, and 99-101 are allowable. Claims 102-171 are free of the prior art, but are rejected for other reasons.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

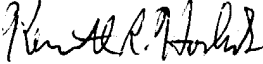
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 Ph.D.  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

10/06/04